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the tubular shaft member is a hypotube made from nickel-titanium

alloy.

REMARKS

This Amendment is in response to the Office Action dated September 20, 2002. Claims 1-21 are pending in this application. By this Amendment, Applicants have amended claims 2, 3, 4, 6, 7, 11 and 17 to address the claim objections raised by the Examiner in the Office Action. These amendments were not made for the purpose of distinguishing the claimed invention over the cited prior art. Claim 17 was amended to include the recitation that the filtering assembly is mounted to a tubular shaft member having a lumen for receiving a guide wire. Claim 19 also was amended to reflect the amendment made to claim 17. New claims 22-26 are being submitted for consideration by Examiner. Reconsideration of all of the pending claims is respectfully requested.

The Examiner has rejected claims 1-6, 8-14 and 16 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,814,064 to Daniel et al. (the "Daniel '064 patent"). Applicants strongly disagree with the Examiner's characterization of the various components shown in the Daniel '064 patent. Specifically, the Examiner has relied on FIGS. 16A and 16B as the basis for rejecting the claims. However, the particular combination of elements recited in the pending claims are not shown in

FIGS. 16A and 16B. Rather, the distal end of the sheath 204 is not attached to the guide wire 194 in either of the embodiments of FIGS. 16A or 16B since it appears that the guide wire 194 must extend through the sheath 204 in a sliding relationship in order for the filter actuating mechanism to function properly. An actuator wire 196 is shown attached to the sheath 204 in both figures of the Daniel '064 patent in order to move the sheath 204 relative to the filter assembly 198 to collapse or expand the filter assembly 198 as desired. In this regard, the sheath 204 cannot be fixedly attached to the guide wire, but rather, must maintain a sliding relationship with the sheath 204 in order to allow the sheath 204 to be moved relative to the filter assembly 198 which is maintained in a fixed position on the guide wire 194. Additionally, the Daniel '064 patent fails to show a tubular shaft member which is moveable along the guide wire in a coaxial arrangement as recited in claim 1 and the dependent claims. Rather, a single wire is used as an actuating wire 196 in the embodiment of FIGS. 16A and 16B. While FIG. 15 of the Daniel '064 patent may show a tubular shaft 178, this particular embodiment is not used in any manner with a sheath, no less a sheath attached to a guide wire. Accordingly, none of the embodiments of the Daniel '064 patent relied upon by the Examiner show the particular combination of elements recited in the pending claims.

The Examiner has relied upon FIG. 1 of the Daniel '064 patent as an alternative basis for showing the operation of the filter device. However, this particular

embodiment in the Daniel '064 patent does not utilize a sheath attached to a guide wire.

Rather, the actuation of the filter assembly is accomplished by introducing or

withdrawing inflation fluid through a hollow guide wire 14. Accordingly, Applicants

believe that the Daniel '064 patent should be withdrawn as an anticipatory reference to all of the claims at issue.

Claims 1, 2, 4, 5, 7-9, 11, 12, 14, 17-18, were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,171,328 to Addis (the "Addis patent"). Again, Applicants strongly disagree with the Examiner's characterization of the elements shown in the Addis patent. The Addis patent shows a catheter 10 which includes an atraumatic floppy tip 15 mounted at the distal end 12 of the catheter (see col. 5, lines 16-21). In this regard, the catheter 10, which the Examiner has identified as corresponding to the tubular shaft recited in the pending claims, acts both as a catheter and a guide wire. Moreover, the actuating mechanism 29, which the Examiner has characterized as a guide wire, does not function as a guide wire at all, but rather, is utilized as an actuating mechanism for moving the actuating mechanism 40 associated with the filter 20. This wire element is clearly identified as an actuating mechanism 29 in the Addis patent. Additionally, the capture sheath 36 of the Addis patent is not attached to the guide wire, as called for by the claims, but rather, appears to be attached to the catheter 10. Accordingly, the Addis patent fails to disclose the particular combination of

elements defined in the present claims. Applicants believe that the Addis patent also should be withdrawn as an anticipatory reference.

Claims 1-6 and 10-15 also were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. (the "Daniel '327 patent").

Again, Applicants strongly disagree with the Examiner's characterization of the elements found in the Daniel '327 patent. The Examiner has characterized the embodiment of FIG. 1 in the Daniel '327 patent as showing a guide wire 26 with filter 21 attached distally and a tubular shaft 12. However, the delivery catheter 12 utilized in the Daniel '327 patent utilizes a filter housing 18 which is designed to collapse or constrict the filter 21. This filter housing 18 is not attached to the guide wire, but rather, is slidably disposed on the guide wire to allow the catheter 12 and housing 18 to be removed from the guide wire once the filter is to be deployed. In this regard, the housing 18 of the Daniel '327 patent is not attached to the guide wire. For this reason alone, the Daniel '327 patent fails to show the particular combination of elements recited in the claims at issue. The Examiner has relied on FIGS. 13 and 15 as showing a sheath (440 or 640) that is flared outward in a proximal direction for receiving the filter. However, this particular element (sheath 440 or 640) is not used to constrict the filtering assembly, but rather, is utilized as a nose cone to provide a tapered profile to the delivery system. Rather, in the Daniel '327 patent, the filter housings 418 and 618 shown in FIGS. 13 and

15 are utilized to constrict the filter element. Moreover, the tubular shaft 12 shown in the Daniel '327 patent is not attached to the filtering assembly, but rather, remains in a sliding coaxial relationship over the filtering assembly 10. Accordingly, the particular combination of elements in the claims at issue is not shown in the Daniel '327 patent. Applicants submit that the Daniel '327 patent should be withdrawn as an anticipatory reference.

Claims 17-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Addis patent in view of the Daniel '064 patent. As discussed above, the Addis patent fails to disclose the basic combination of elements forming the filtering device defined in claims 17-21. Moreover, the Examiner's reliance on the use of Nitinol hypotube (318 or 322) in the embodiment of FIG. 20A of the Daniel '064 patent as a basis for suggesting that it can be used as an alternative to a guide wire is somewhat misplaced. In the embodiment of FIG. 20A of the Daniel '064 patent, the Nitinol hypotube 318 is utilized as a means for allowing pressurized fluid to enter a balloon 316 to cause expansion of the filter frame 314 and mesh 312. This hypotube 318 is not utilized in conjunction with any type of restraining sheath since a sheath is not needed because the filtering assembly moves between an expanded and collapsed position via fluid actuation. Therefore, it would not have been obvious by one skilled in the art at the time the invention was made to merely substitute the guide wire 14 of the Addis patent

with a hypotube, as suggested by the Examiner. Moreover, since the Addis patent does not disclose the basic combination of elements forming the filtering device, the resulting combination of Addis and Daniel '064 patents does not achieve the particular method recited in these pending method claims.

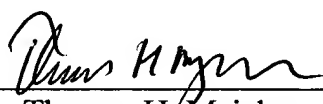
New presented claims 22-26 define a combination of elements which is neither shown nor suggested by the cited prior art references. Therefore, Applicants believe that these claims are patentably distinct from the cited prior art.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at 310-824-5555 to facilitate prosecution of this application, if necessary.

Attached hereto is a marked up version of the changes made to the

specification and claims by the current Amendment. The attached page is captioned
"Version With Markings To Show Changes Made."

Respectfully submitted,
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“VERSION WITH MARKINGS TO SHOW CHANGES MADE”

2. (Amended) The filtering device of claim 1, wherein:

the filtering assembly has a plurality of [spines] splines disposed in annularly spaced relationship to one another and has a filter member attached to the spines.

3. (Amended) The filtering device of claim 2, wherein:

the [spines] splines are formed from a material having shape memory for disposition against the vessel when released from the sheath and the filter member is formed from a material having properties of passing the fluid in the vessel while blocking the passage of emboli in the vessel.

4. (Amended) The filtering device of claim 1, wherein:

the filtering assembly [become] becomes disposed within the sheath when the tubular shaft member becomes disposed within the sheath.

6. (Amended) The filtering device of claim 2, wherein:

the [spines] splines are self expanding.

11. (Amended) The filtering device of claim 1, wherein:

the tubular shaft member is made from a material having flexible properties and properties of withstanding buckling[.].

17. (Amended) A method of passing fluid in a vessel and of preventing emboli in the fluid from passing through the vessel from a lesion in the vessel, including the steps of:

providing a filtering assembly having constricted and expanded positions and having properties in the expanded position of passing fluid while blocking the passage of emboli from the lesion, the filtering assembly being mounted to a tubular shaft member having a lumen for receiving a guide wire.

disposing the filtering assembly in a sheath attached to a guide wire in the constricted position with the filtering assembly disposed in the sheath and movable relative to the sheath, the guide wire being disposed and movable within the lumen of the tubular shaft member.

positioning the filtering assembly and the sheath in the vessel at a position past the lesion in the direction of the fluid flow in the vessel,

producing relative movement between the sheath and the filtering assembly in a direction to move the filtering assembly in the expanded position, and

expanding the opening in the vessel at the position of the lesion with an interventional device while the filtering assembly remains in the expanded relationship to provide for the operation of the filtering assembly in passing the fluid while blocking the passage of emboli created during the expansion of the opening in the vessel.

19. (Amended) A method as set forth in claim 18, wherein:

the filtering assembly is disposed in a fixed relationship on the tubular shaft member and the tubular shaft member is a hypotube,

the hypotube is made from a flexible material having properties of withstanding buckling, and

the distal end of the hypotube becomes disposed within the sheath when the filtering assembly is placed into the sheath.